

510(k) Summary

Submitter: Medtronic Advanced Energy
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DEC 03 2013

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Date Summary Prepared: September 18, 2013

Device Trade Name: Aquamantys® 2.3 Bipolar Sealer
Aquamantys® EVS 4.0 Epidural Vein Sealer
Aquamantys® Mini EVS 3.4 Epidural Vein Sealer
Aquamantys® SBS 5.0 Sheathed Bipolar Sealer

Common Name: Electrosurgical Instrument

Classification Name: Electrosurgical cutting and coagulation device and accessories

Predicate Device: (Codman Irrigated Bipolar Forceps)
K896541 Malis Bipolar Electrosurgical System CMC III
(Medtronic Advanced Energy Aquamantys Bipolar Sealers)
K052859 Aquamantys 2.3 Bipolar Sealer
K063639 Aquamantys EVS 4.0 Epidural Vein Sealer
K063639 Aquamantys Mini EVS 3.4 Epidural Vein Sealer
K111732 Aquamantys SBS 5.0 Sheathed Bipolar Sealer

Device Description: The Aquamantys Bipolar Sealer is a sterile, single-use bipolar device. The device employs radio-frequency (RF) energy and saline irrigation for hemostatic sealing and coagulation. The device is equipped with a dual electrode tip. Saline and electrical lines exit the opposite end of the handpiece from the electrodes. The handpiece is equipped with an on-off button that simultaneously activates both RF and saline flow. A saline fluid delivery line is provided with the device, and includes a section of pump tubing and drip chamber or spike. The three-pin electrical connector is designed to be plugged into the Aquamantys Pump Generator.

Intended Use: The Aquamantys Bipolar Sealer is a sterile, single-use bipolar electrosurgical device intended to be used in conjunction with the Aquamantys Pump Generator for delivery of RF energy and saline for hemostatic sealing and coagulation of soft tissue and bone at the operative site. It is intended for, but not limited to orthopaedic, neurosurgical, spine, endoscopic procedures [except AQM 2.3], abdominal [open abdominal for AQM 2.3] and thoracic surgery, and epidural vein sealing [3.4, 4.0 & 5.0 only] during surgery. The device is not intended for contraceptive tubal coagulation (permanent female sterilization).

**Technological
Characteristics:**

The Aquamantys Bipolar Sealers have the same technological characteristics as the Codman Irrigated Bipolar Forceps. Both devices are bipolar electrosurgical instruments that employ radio-frequency (RF) energy and saline irrigation for hemostatic sealing and coagulation.

Non-Clinical Tests:

Comparative performance data was conducted on ex-vivo porcine brain tissue. Thermal zone damage of the Aquamantys Bipolar Sealers was comparable to the thermal zone damage of the Codman Irrigated Bipolar Forceps.

Clinical Tests:

Clinical studies were not required or conducted to support the proposed neurosurgical expanded indications.

Conclusion:

The indications for use, technology and performance characteristics of the Aquamantys Bipolar Sealers are the same as the Codman Irrigated Bipolar Forceps. Based on this, Medtronic Advanced Energy claims substantial equivalence to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-C609
Silver Spring, MD 20993-0002

Medtronic Advanced Energy
Ms. Gabriela Anchondo
Senior Regulatory Affairs Specialist
180 International Drive
Portsmouth, New Hampshire 03801

December 3, 2013

Re: K132974

Trade/Device Name: Aquamantys 2.3 Bipolar Sealer, Aquamantys EVS 4.0 Epidural Vein Sealer, Aquamantys Mini EVS 3.4 Epidural Vein Sealer, Aquamantys SBS 5.0 Sheathed Bipolar Sealer

Regulation Number: 21 CFR 878.4400

Regulation Name: Electrosurgical cutting and coagulation device and accessories

Regulatory Class: Class II

Product Code: GEI

Dated: November 15, 2013

Received: November 18, 2013

Dear Ms. Anchondo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Joshua C. Nipper -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.

For Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132974

Device Name:
Aquamantys 2.3 Bipolar Sealer

Indications for Use:

The Aquamantys 2.3 Bipolar Sealer is a sterile, single-use, bipolar electrosurgical device intended to be used in conjunction with the Aquamantys Pump Generator for delivery of RF energy and saline for hemostatic sealing and coagulation of soft tissue and bone at the operative site. It is intended for, but not limited to orthopaedic, neurosurgical, spine, thoracic, and open abdominal surgery. The device is not intended for contraceptive tubal coagulation (permanent female sterilization).

Device Name:
Aquamantys Epidural Vein Sealer & Aquamantys Mini Epidural Vein Sealer

Indications for Use:

The Aquamantys Epidural Vein Sealer is a sterile, single-use bipolar electrosurgical device intended to be used in conjunction with the Aquamantys Pump Generator for delivery of RF energy and saline for hemostatic sealing and coagulation of soft tissue and bone at the operative site. It is intended for, but not limited to orthopaedic, neurosurgical, spine, endoscopic procedures, abdominal and thoracic surgery, and epidural vein sealing during surgery. The device is not intended for contraceptive tubal coagulation (permanent female sterilization).

Device Name:
Aquamantys SBS 5.0 Sheathed Bipolar Sealer

Indications for Use:

The Aquamantys SBS 5.0 Sheathed Bipolar Sealer is a sterile, single-use bipolar electrosurgical device intended to be used in conjunction with the Aquamantys Pump Generator for delivery of RF energy and saline for hemostatic sealing and coagulation of soft tissue and bone at the operative site. It is intended for, but not limited to orthopaedic, neurosurgical, spine, endoscopic procedures, abdominal and thoracic surgery, and epidural vein sealing during surgery. The device is not intended for contraceptive tubal coagulation (permanent female sterilization).

Prescription Use
(Per 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use
(Per 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H.
Chen -A

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Certified by FDA, our People, as = Long H. Chen
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Date: 2018.05.15 14:17:19 -05'00'

for BSA

(Division Sign-off)
Division of Surgical Devices
510(k) Number K132974